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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,784	11/28/2001	Akira Yamamoto	P21675	8367

7055 7590 09/09/2003

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EXAMINER
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BELYAVSKIY, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/994,784

Applicant(s)

YAMAMOTO ET AL.

Examiner

Michail A Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 16-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### DETAILED ACTION

Claims 1- 30 are pending.

I. Applicant's election with traverse of Group II (claims 1-15) in Paper No. 9 is acknowledged.

Applicant traverse the Restriction Requirement on the grounds that the search of Groups I-IV together would not constitute a serious search burden on the examiner and that search of the claims of Group II would provide useful information for the claims of Group I and Group II and IV. This is not found persuasive because the MPEP 803 (August 2001) states that "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The Restriction Requirement enunciated in the previous Office Action meets this criteria and therefore establishes that serious burden is placed on the examiner by the examination of more than one Group. The Inventions are distinct for reasons elaborated in paragraphs 2-5 of the previous Office Action and above

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 16-30 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

*Claims 1-15 drawn to a carrier having immobilized antibodies are under consideration in the instant application.*

3 The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*.

4. The abstract of the disclosure is objected to because it exceeds 150 words in length. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said,"

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should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112.

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

6. Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite in the recitation of "... in which each antibody is immobilized to the carrier through the ligand and the antiligand". It is unclear if antibody is immobilized to the carrier by binding separately to ligand and to antiligand or it is immobilized through a pair of ligand/antiligand which can be bounded with each other in a specific manner thus only ligand is bound to the antibody ?

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

8. Claims 1 and 5-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitano et al (GB 2282548) or by Mitoh et al (GB2307552, IDS).

GB '548 teaches a carrier having a surface formed of a calcium phosphate compound and antibody, immobilized on the surface through an irrelevant portion thereof, wherein the carrier surface has a portion wherein the antibodies are not immobilized and at least a part of the portion of the surface is coated with a protein having low interaction with antibodies (see entire document, Abstract in particular). GB '548 teaches a protein having low interaction with antibodies that is casein (see page 19 in particular). GB '548 teaches a carrier having immobilized antibodies wherein antibodies are stabilized by treating the carrier with stabilizing agent and the cross-linking agent that is glutaraldehyde (see overlapping pages 18-19 in particular). GB '548 teaches a carrier, wherein carrier is produced by colliding porous particles of calcium phosphate (see pages 8, 10 and example 1 in particular).

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The reference teaching anticipates the claimed invention.

Similarly, GB'552 teaches a carrier having a surface formed of a calcium phosphate compound and antibody, immobilized on the surface through an irrelevant portion thereof, wherein the carrier surface has a portion wherein the antibodies are not immobilized and at least a part of the portion of the surface is coated with a protein having low interaction with antibodies (see entire document, Abstract in particular). GB'552 teaches a protein having low interaction with antibodies that is casein (see page 6 in particular). GB'552 teaches a carrier having immobilized antibodies wherein antibodies are stabilized by treating the carrier with stabilizing agent and the cross-linking agent that is glutaraldehyde (see page 6 in particular). GB'552 teaches a carrier, wherein carrier is produced by colliding porous particles of calcium phosphate (see pages 5, and examples 1 and 2 in particular).

The reference teaching anticipates the claimed invention.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitano et al (GB 2282548) or Mitoh et al (GB2307552, IDS) each in view of Nakayama et al (US Patent 5,827,669) and further in view of Jonson et al (US Patent 4,885,207).

The teaching of GB'548 and GB'552 have been discussed, supra.

GB'548 and GB'552 do not teach a carrier wherein carrier has antigens thereon and an antibody has a ligand bonded thereto and antibody immobilized to the carrier through ligand/antigen interaction, or wherein the antibodies are IgG.

US Patent '669 teaches a carrier, wherein said carrier have a surface which is formed of a calcium phosphate based compound with antigens, such as avidin, or streptavidin being adsorbed and immobilized thereon (see entire document, Abstract and column 1, lines 30-68).

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and column 2, lines 40-60 in particular). US Patent '669 teaches an antibodies that have a ligand bonded thereto wherein a ligand is biotin that is immobilized to the carrier through biotin-avidin interaction ( see, column 2, lines 1-5 and column 5, line 15-27 in particular). US Patent '669 teaches the avidin or streptavidin or derivatives thereof have a notable high affinity to a biotin and biotin can be easily bonded with antibody. Based on this specific properties a carrier was made in which antibody was immobilized with a good and right orientation. The good and right orientation is the result of the reaction between the avidin (antiligand) that was immobilized on the carrier and the biotinylated (ligand-bound) antibody. Using this carrier an easily and high sensitive detection can be performed (see column 5, lines 15-26 in particular).

US Patent '207 teaches a carrier having immobilized antibody, wherein antibody are IgG. ( see entire document, column 7, lines 5-10 in particular). US Patent '207 teaches that there is a pragmatic need to maximized antibody loading and right orientation of said antibody on the carrier for optimizing process efficiency ( see column 2, lines 1-15 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '669 and US Patent '207 to those of GB'548 or GB'552 to obtain a claimed carrier having immobilized antibodies wherein the carrier has antiligands thereon and antibody has a ligand bonded thereto and wherein antibody is immobilized to the carrier through the ligand and the antiligand interaction and wherein antibody is IgG.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because there is a pragmatic need to maximized antibody loading and right orientation of said antibody on the carrier, including IgG, for optimizing process efficiency as taught by US Patent '207 and the good and right orientation is the result of the reaction between the avidin (antiligand) that was immobilized on the carrier and the biotinylated (ligand-bound) antibody as taught by US Patent '669. This type of the carrier can substitute the carrier taught by GB'548 and GB'552 for easily and high sensitive detection.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. No claim is allowed.


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11. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. For example, the word "biotin" is misspelled on page 18, lines 1 and 7. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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September 8, 2003

  
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